MedTrade *Products* Ltd

K072328

510(k) SUMMARY: MedTrade CELOX Topical Hemostatic Granules in Soluble Bag
Classification Name: 878 – General and Plastic Surgery
Contact: Jonathan Ranfield - Director, Quality Assurance & Regulatory Affairs
Prepared: August 10, 2007.

DEC 2 1 2007

Description: MedTrade Products CELOX Topical Hemostatic Granules and MedTrade Products CELOX Topical Hemostatic Granules in Soluble Bag are essentially the same product. In that the CELOX Topical Hemostatic Granules are exactly as in our 510(k) K061079 and the Soluble Bag prevents any accidental spillage of the granules whilst opening the sachet and provides a controlled and accurate delivery System to ensure that the CELOX Topical Hemostatic Granules are applied directly onto the wound site as quickly and efficiently as possible. On contact with liquid the soluble bag will dissolve in 30 to 70 seconds

MedTrade CELOX Topical Hemostatic Granules in Soluble Bag are intended as a temporary external wound treatment for the control of severely bleeding wound for emergency use and are intended for emergency use as an external temporary traumatic wound treatment to achieve Hemostatis and prevent blood loss. The product is designed and packaged to be easily packed, carried and applied using only one hand. It is well suited for moderate to large eviscerating wounds, to create hemolysis by coagulation.

Biocompatibility testing including: Dermal Irritation, Dermal Sensitisation, Cytotoxicity, Acute Systemic Toxicity, Hemolysis, has been conducted on the CELOX Granules Dermal Irritation, Dermal Sensitisation and Cytotoxicity, has been conducted on the Soluble Bag. Cytotoxicity and Systemic Injection have been conducted on the CELOX Granules in the Soluble Bag and the results reported and discussed with the application.

The device is packed in a foil sachet and is provided sterile It is sterilized by gamma irradiation. The product will be sterilised by gamma irradiation in accordance with the Sterilisation of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilisation, 3rd Edition ANSI/AAMI/ISO11137-1994) and Microbiological Methods for Gamma Sterilisation (AAMI TIR8-1991) Qualification will be based on Method 1 for dosimetric release with a sterility assurance level of 10^{-6}. The product will receive a dose of 25gKys to 35kGys.

MedTrade Products CELOX Topical Hemostatic Granules in Soluble Bag are identical in chemistry and technology to MedTrade Products CELOX Topical Hemostatic Granules K061079 and substantially equivalent in physical state and application via bag to Z-Medica Corporation QuikClot ACS K051955. A table of comparative features may be found below.

COMPARATIVE FEATURES

Characteristics	MedTrade *Product's* CELOX Topical Hemostatic Granules	MedTrade *Product's* CELOX Topical Hemostatic Granules in Soluble Bag	Z-Medica's QuikClot ACS
Chemistry	Chitosan, a material consisting of cellulostic polymer, poly-N-acetylglucosamine. This formulation has been self-affirmed by the manufacturer as a GRAS (Generally Recognised As Safe) food ingredient in accordance with 21 CFR s 170.30.	Chitosan, a material consisting of cellulostic polymer, poly-N-acetylglucosamine. This formulation has been self-affirmed by the manufacturer as a GRAS (Generally Recognised As Safe) food ingredient in accordance with 21 CFR s 170.30.	Not Applicable (As it is a synthetic derivative of volcanic rock)
Physical Composition	Granules	Granules in Soluble Bag	Granules in mesh bag
Indications For Use	MedTrade CELOX Topical Hemostatic Granules is Hemostatic Granules for the external temporary control of severely bleeding wounds to achieve hemostasis and prevent blood loss, intended for emergency use. & OTC for Bleeding / Lacerations	MedTrade CELOX Topical Hemostatic Granules is Hemostatic Granules for the external temporary control of severely bleeding wounds to achieve hemostasis and prevent blood loss, intended for emergency use. & OTC for Bleeding / Lacerations	QuikClot is intended for emergency use as an external temporary traumatic wound treatment to achieve hemostasis and prevent blood loss
Packaging	Foil Pouch	Foil Pouch	Foil Pouch
Sterilisation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2007

MedTrade Products, Ltd.
% Mr. Jonathan Ranfield
Director, Quality Assurance
& Regulatory Affairs
Electra House
Crewe Business Park
Crewe, Cheshire,
United Kingdom CW1 6GL

Re: K072328
Trade/Device Name: MedTrade Products CELOX Topical Hemostatic Granules OTC
MedTrade Products CELOX Topical Hemostatic Granules in Soluble Bag
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 12, 2007
Received: December 17, 2007

Dear Mr. Ranfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

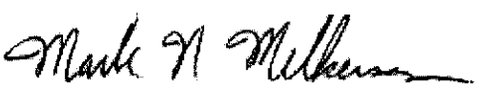
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known) K072328

Device Name: MedTrade Products CELOX Topical Hemostatic Granules in Soluble Bag

Indications for Use:

MedTrade Products CELOX Topical Hemostatic Granules are intended to be used to achieve hemostasis in emergency situations for the temporary control of severe topical bleeding.

Prescription Use_____X_____ AND/OR Over-The-Counter Use_ __
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE, CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072328

Appendix 15

K072328

Indications for Use

510(k) Number (if known) K072328

Device Name: MedTrade Products CELOX Topical Hemostatic Granules OTC

MedTrade Products CELOX Topical Hemostatic Granules are intended to be available Over The Counter for the following indication.

Indications for Use:

MedTrade Products CELOX Topical Hemostatic Granules OTC are indicated for the local management of bleeding such as lacerations, minor cuts and abrasions.

Prescription Use_____ _____ AND/OR Over-The-Counter Use__X___
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE, CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072328